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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,312	10/17/2003	David W. Burke	7404-554	8891
7590		06/20/2007		
Troy J. Cole Bank One Center/Tower Suite 3700 111 Monument Circle Indianapolis, IN 46204-5137			EXAMINER SODERQUIST, ARLEN	
			ART UNIT	PAPER NUMBER
			1743	
			MAIL DATE	DELIVERY MODE
			06/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/688,312

Applicant(s)

BURKE ET AL.

Examiner

Arlen Soderquist

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-6, 9-12, 15-17, 20-26, 29-31, 34-40, 42, 43, 46 and 47 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 7, 8, 13, 14, 18, 19, 27, 28, 32, 33, 41, 44, 45 and 48 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2-14-05, 8-15-05, 2-1-07</u> . | 6) <input type="checkbox"/> Other: ____ |

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1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4-6, 9-12, 15-17 and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Singhal. In the paper Singhal teaches a digital approach for the collection and analysis of electrochemical frequency domain spectra is presented for the oxidation of carbohydrates at a copper electrode using a continuous, large-amplitude sine wave as an excitation waveform (AC signal). The background charging current response is a phase-shifted sine wave with the major frequency component concentrated at the fundamental frequency. A nonlinear faradaic response due to the oxidation of sugars produces significant signal intensities at the higher harmonics as well as the fundamental frequency. Examination of the frequency spectra of glucose and maltose leads to selective and sensitive detection of these sugars at a copper electrode. The selectivity of this measurement relies on the inherent difference in the frequency domain spectra (i.e., magnitude and phase of each harmonic) of sugars of different sizes. This frequency distribution is dramatically affected by temperature, indicating the effect of kinetics in the mechanism for the oxidation of sugars. The sensitivity of the measurement of glucose and maltose is demonstrated with flow injection analysis and post-processing the data with the digital equivalent of a lock-in amplifier. A limit of detection of 8 nM is obtained for glucose when the isolated faradaic current is optimized for phase and frequency. The first page of the article discusses the desire to analyze carbohydrates in biological samples and lists a variety of different known methods. The experimental section describes the apparatus and method used to obtain the results.

3. Claims 36-40, 42-43 and 46-47 are rejected under 35 U.S.C. 102(b) as being anticipated by de Vries. In the paper de Vries discusses implications of the dielectrical behavior of human blood for continuous online measurement of hematocrit. A study was designed to explore the possibility of detecting the hematocrit of blood by means of admittance measurements. The admittance and phase angle of blood kept in a measuring cell were determined at various frequencies between 60 kHz and 24 MHz. A reliable and accurate estimation of hematocrit was obtained in two ways. First, low-frequency admittance, high-frequency admittance and a factor

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x, which was the conductive percentage of cell content, were used. Secondly, the maximum phase angle was used. Figure 3 shows the phase response of the applied frequencies for different values of hematocrit. Figure 5 shows the correlation between hematocrit and the phase angle. Both methods can be applied to obtain continuous on-line information about hematocrit for blood volume control during hemodialysis.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 22-26, 29-31, 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singhal as applied to claims 1, 4-6, 9-12, 15-17 and 20-21 above, and further in view of Bodai (US 4,929,426), Doss and de Vries as explained above. Singhal does not teach a temperature or hematocrit correction.

In the patent Bodai teaches a portable apparatus for measuring the electrochemical characteristics of a sample. A disposable cartridge, including a plurality of interconnected flow chambers, houses a printed circuit board substrate upon which reference and indicating electrodes are formed. The electrodes are employed in the presence of chemical reagents to aid in the electrochemical determination of a sample undergoing analysis. A thermal sensing element is in close proximity to the electrodes to permit the correction of the measurement for variations in temperature. After a pH value has been determined, the used cartridge can be mechanically ejected thus eliminating user exposure to the blood sample being measured. In this way, the pH of a blood sample can be determined quickly, effectively, inexpensively and with a

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minimum amount of sample and reagent preparation. Column 5, lines 56-60 discuss the temperature and other corrections. Element 42 is the temperature sensor. Column 9, lines 42-49 discuss the presence of at least one reagent. Column 16, line 48 to column 11, line 7 discusses the temperature measurement and the application of a temperature correction to the measurement from each of the electrodes present in the device. Column 12, lines 45-49 clearly teach the presence of electrodes for measuring other parameters of the blood sample.

In the paper Doss discloses a hyperthermia applicator intended for complete implantation and long-term use. Radio frequency energy is transmitted from an external antenna to a closely coupled subdermal antenna. This internal antenna is connected via a transmission line to deeply implanted electrodes. Changes in temperature at the electrodes result in a change in tissue resistivity which modifies the complex impedance seen at the external antenna terminals. This variation in antenna impedance (magnitude and/or phase angle) can, in principle, be utilized to indirectly monitor and regulate tissue temperature at the electrode location. Test results from conductive-gel tissue phantom experiments are presented.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the temperature measurement method of Doss and the hematocrit measurement method of de Vries into the Singhal method because of the ability to measure the temperature and hematocrit without providing anything more than the electrodes already present and an AC signal generator/analyzer as shown by Doss and de Vries and the need to correct for temperature variation as taught by Bodai.

6. Claims 2-3, 7-8, 13-14, 18-19, 27-28, 32-33, 41, 44-45 and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The art of record fails to teach or fairly suggest the methods as claimed in these claims.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art relates to measuring hematocrit and the differences between admittance and impedance.

8. It is noted that the IDS submitted by applicant has several listed references lined through. Where it is clear that the reference had a date that was not usable, the reference was not submitted by applicant, a foreign reference was not submitted with a translation or explanation as

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required or the citation was a duplicate, the references have been lined through. If applicant feels that one or more of these references is particularly relevant to the claimed invention, the reference should be listed in an IDS with the relevance clearly noted. It is also noted that around 1/3 of the references were lined through for the above reasons.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Arlen Soderquist
Primary Examiner
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